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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,595	11/30/2005	John Ong	0501-UTL-0	2750

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Intellectual Property Department
Amylin Pharmaceuticals, Inc.
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EXAMINER	
HA, JULIE	

ART UNIT	PAPER NUMBER
1654	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,595	ONG ET AL.	
	Examiner	Art Unit	
	JULIE HA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) *11-14 and 35-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 15-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/20/06 and 3/14/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Election/Restriction filed on May 28, 2008 is acknowledged. Claims 1-50 are pending in this application.

Restriction

1. Applicant's election with traverse of Group I (claims 1-10 and 15-34) and election of exendin-4 (SEQ ID NO:2), poly-arginine for cationic poly-amino acid, tonicifying agent for the agent, hydroxypropyl methylcellulose for viscosity-increasing agent, carbomer for bioadhesive agent, phenylethyl alcohol for preservative, and weight loss for the disease to be treated in the reply filed on May 28, 2008 is acknowledged. The traversal is on the ground(s) that "the specific sequence of the peptide or protein is not relevant to the invention...it is not necessary to search a 'structural core'. The claims recite a pharmaceutical composition containing, among other ingredients, a 'bioactive peptide or protein'. Proper examination of the claims does not require searching for a particular sequence of a bioactive peptide or protein. Rather, it requires searching generically for a pharmaceutical composition containing the elements recited in the claim, including a bioactive peptide or protein, which sequence is not specified by the claim because the composition is applicable to any peptide or protein sequence and its effectiveness is not determined by said sequence." This is not found persuasive because the sequence of each and every bioactive peptide or protein is patentably independent and distinct due to their different amino acid content. When a sequence of GLP-1 is searched, it would not necessarily lead to a pharmaceutical composition comprising a bioactive agent that

is erythropoietin (EPO). An EPO is a glycoprotein hormone that is bioactive. Thus, search for one would not necessarily lead to the other.

2. Furthermore, as described in the previous office action (see pp. 4-5), Groups 1-9 do not related to a single general inventive concept under PCT Rule 13.2, because they lack the same or corresponding special technical features. The bioactive peptides and proteins claimed in the invention do not share a core sequence. For example exendin-4 has the sequence HGEGTFTSDLSKQMEEEAVRLFIEWLKNGGPSSGAPPPS and PYY has the sequence YPAKPEAPGEDASPEELSRYYASLRHYLNLVTRQRY. Since the two peptides do not share a core structure, the inventions lack a special technical feature (see previous office action mailed April 28, 2008). Search for one would not necessarily lead to the other.

3. Applicant appears to be indicating that if a pharmaceutical composition comprising a GLP-1 is found than this meets the limitation of any other bioactive peptide in a pharmaceutical composition. For example, if a prior art is found teaching a pharmaceutical composition of a GLP-2 and a poly-lysine in a saline, then this reference would be an obvious variant of claims 1-3, 6-14 etc. Applicant is directed to paragraph 12 on page 7 of the Election/Restriction requirement mailed on April 28, 2008. **"Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either case, if the examiner finds one of the inventions**

unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention."

The requirement is still deemed proper and is therefore made FINAL. Claims 11-14 and 35-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected invention, there being no allowable generic or linking claim. Claims 1-10 and 15-34 are examined on the merits in this office action.

Objection-Minor Informalities

4. The title is objected to for the following reasons: Section 606 of the MPEP states that the title of the invention should not begin with the word "Novel" or "New". Currently, the invention is entitled "Novel Methods and compositions for the Enhanced Transmucosal Delivery of Peptides and Proteins". Appropriate correction is required.

5. Claim 1 is objected to for the following minor informality: Claim 1 recites, “A pharmaceutical composition…a composition said compatible buffer does not cause precipitation of the cationic polyamino acid…” at lines 4-5 of the claim. There appears to be grammatical error at line 4 of the claim. Appropriate correction is required.

6. Claim 8 is objected to for the following minor informality: Claim 8 recites, “the composition of claim 7…average molecule weight of between about 10 kDa and about 200 kDa”. There appears to be a grammatical error at line 2 of the claim. The term "average molecule weight" should be corrected to "average molecular weight".

7. Claims 27 and 31 are objected to for the following minor informalities: There appear to be punctuation errors at lines 3-4 of the claims. Claims 27 and 31 both recite, “0.56% monosodium glutamate, monohydrate (w/v) at a pH of about 4.5". The comma should appear after monohydrate (w/v) (i.e., 0.56% monosodium glutamate monohydrate (w/v),). Appropriate correction is required.

8. Claims 19-21 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The MPEP states the following: Claim scope is not limited by claim language that suggests or makes optional but does not require steps to be performed, or by claim language that does not limit a claim to a particular structure…examples of claim languages, although not exhaustive, that may raise a question as to the limiting effect of the language in a claim are: (A) “adapted to” or “adapted fro” clauses; (B) “wherein” clauses; and (C) "whereby" clauses (see MPEP 2111.04). In the instant case, the "wherein" clause recited in claims 19-21 does not result in a structural difference and therefore, the claims do not further limit claim 1.

Rejection-35 U.S.C. 112, 2nd

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 22-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claim 22 recites, "…wherein at of between about pH 4.0 and about 5.0…." at lines 5-6 of the claim. The phrase, "wherein at of between" is unclear. It is unclear if a word is missing or if some of the phrase should be deleted or if there was some type of typographical error. In the current form, the wherein clause is unclear and the applicant's intent is unclear. Because claims 23-26 depend from indefinite claim 22 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Rejection-35 U.S.C. 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Rothbard et al (US 2002/0009491 A1).

14. Rothbard et al teach a pharmaceutical composition comprising components (delivery-enhancing transporter (poly-arginine) and biologically active agents (such as peptide or protein)) in a suitable medium, such as water or a buffered aqueous solution (see paragraphs [0026], [0038] and [0123]). Since the bioactive peptide and cationic polyamino acid are formed in water or aqueous buffer, this would inherently have the functionality and the characteristics of the instantly claimed invention.

15. Claims 1-4, 6-7, 9-10, 15-16 and 18-21 are rejected under 35 U.S.C. 102(a) as being anticipated by Defelippis et al (WO 02/098348, filed in the IDS).

16. Defelippis teaches a composition comprising a GLP-1 compound and a basic polypeptide (see claim 1). Defelippis specifically teaches the use of exendin-4 (see claim 8, page 12, lines 6-21) as the GLP-1 compound. Defelippis teaches polyarginine as the basic polypeptide (see claim 13). Further, Defelippis teaches that the composition is in a buffered solution (see page 27, lines 18-20) and teach solutions for injection (see page 31, lines 7-10). This meets the limitation of claims 1, 7 and 9-10. Defelippis teaches the use of a zinc solution at pH of between about 5 and about 6 (see page 29, lines 29-32) and also teaches pH adjustments to less than 5 (see page 31, lines 14-15) and the use of an acetate buffer (see page 29, lines 23-24), meeting the limitations of claims 2-4. Further, Defelippis teaches that use of sucrose (see page 33, line 2) in the composition, meeting the limitation of claim 15. Additionally, Defelippis

teaches the use of starch (see page 35, line 1) in the composition, and the use of phenol (see page 31, line 1) and the use of in the composition, meeting the limitations of claims 6, 16 and 18. The instant specification discloses that "exemplary viscosity-increasing and bioadhesive agents that may be used in the compositions discloses herein, include, but are not limited to cellulose derivatives...starch, gums, carbomers, and polycarbophil..." (see paragraph [0210] of instant specification US 2006/0172001 A1). Since bioadhesive includes starch, which is disclosed by Defelippis reference, this meets the limitation of claim 6. Claims 19-21 do not further limit the structural limitation of the compound, therefore, claims do not further limit claim 1. Therefore, Defelippis meet the limitations of claims 19-21 of the instant claims.

17. Claims 1-4, 6-7, 9-10, 15-16 and 18-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Defelippis et al (WO 02/098348).

18. The teachings of Defelippis is described, supra. Therefore, Defelippis teachings meet the limitations of claims 1-4, 6-7, 9-10, 15-16 and 18-21 of instant application.

35 U.S.C. 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

21. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

22. Claims 1-10 and 15-26 rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al (US 2003/0087820 A1, filed in the IDS) in view of Baichwal AR (US Patent No. 5,330,761) and Ryser et al (US Patent No. 4,847,240, filed in the IDS).

23. Young discloses a pharmaceutical composition for using exendin-4 for transmucosal administration (see paragraph [0188]) using an acetate/glutamate buffer (comprises acetic acid/glutamic acid), with a pH in the range of 3-7 (see paragraph [0203]) and further ingredients including mannitol (tonicifying agent), m-cresol (preservative), methylcellulose (viscosity-increasing agent) and other excipients as

needed, such as sodium chloride (see paragraph [0203]). Young teaches that the dosage forms preferably include approximately 0.005 to about 5%, of the active ingredient in an aqueous system along with approximately 0.02 to 0.5% (w/v) of an acetate, phosphate, citrate or glutamate or similar buffer either alone or in combination to obtain a pH of the final composition of approximately 3.0 to 7.0 (see paragraph [0203]). This meets the limitation of claims 1-5, 6 in part, 9-10, 15-16, 18-24 and 26. The difference between the reference and the instant claims is that the reference does not teach a bioadhesive agent and the polyarginine and the range of molecular weights of the polyamino acids, tonicifying agent, viscosity-increasing agent, bioadhesive agent and preservative (Young's ranges overlap the instantly claimed ranges).

24. However, Baichwal AR teaches that a bioadhesive controlled-release solid dosage forms adhere to mucosa (especially in the oral cavity, but also e.g. in periodontal pockets, surgical wounds etc) to provide controlled release of analgesics, anti-inflammatories, anti-tussives, hormone, antibiotics, etc. Further, Baichwal teaches that the bioadhesive controlled release excipients are directly compressible into tablet formulations which are not absorbed into body but provides a localized effect (see basic abstract enclosed).

25. Further, Ryser teaches that it is well known that many molecules of a wide variety are not transported, or are poorly transported, into living cells. Macromolecules, for example, such as proteins, nucleic acids, and polysaccharides are not suited for diffusion or active transport through cell membranes simply because of their size (see column 1, lines 22-27). Ryser teaches that cationic polypeptides, and in particular

polyarginine effect or enhance cellular uptake of molecules which are either excluded from or are poorly taken up by cells (see column 1, lines 48-65 and column 4, lines 12-12-18). Ryser teaches that for some proteins as much as a factor of several hundred fold and dramatically increases cellular transport of molecules such as drugs co-factors nucleotides and nucleotide analogs, gaining a very important advantage by using selected cationic polymers, such as poly-L-lysine and poly-L-arginines, which are excellent substrates for physiological proteolytic enzymes present in mammalian cells, i.e. after having served as a transport carrier, they can be digested or otherwise broken down inside the cells into normal physiologic by-products (see columns 3-4, specifically, column 4, lines 29-34). Ryser further discloses that there are wide variety of molecules which can be covalently bonded to cationic polymers including, peptides and that typically the positively charged groups are primary, secondary, or tertiary amines which ionize at or around neutral pH (the range claimed to prevent precipitation), and that cationic poly(amino acids) are preferred because of the outstanding enhancement in cellular uptake which they provide along with the digesting by proteolytic enzyme some poly(amino aid), i.e. polyarginine, provide (see columns 5-6). Ryser teaches that polycationic amino acids have multiple uses including chemotherapeutic applications, anti-microbial application, for genetic diseases, enhancing cellular uptake or polypeptide hormones, such as insulin, cellular transport for other molecules having biological functions (see columns 15-16).

26. Therefore, it would have been obvious to one of ordinary skill in the art to combine the teachings of Young, Baichwal and Ryser for the express benefits for

enhancing cellular uptake of polypeptide hormones across membranes, for controlled release, and for the adhesion of the bioactive agents to the mucosa of the patient population (oral cavity, etc). Young reference indicates that delivery of peptide drugs is often difficult because of factors such as molecular size, susceptibility to proteolytic breakdown, rapid plasma clearance, peculiar dose-response curves...and the tendency of peptides and proteins to undergo aggregation, adsorption, and denaturation. Thus, there continues to exist a need for the development of alternative methods to the inconvenient, sometimes painful, injection for administration of peptide drugs (i.e., better transmucosal routes of administration is necessary because the properties of peptides and proteins make them difficult to utilize) (see paragraph [0009]). One of ordinary skill in the art would have been motivated to combine the teachings since Ryser teaches that cationic polypeptides (polyarginines) enhance the cellular uptake of molecules which are either excluded from or are poorly taken up by cells (some proteins as much as by a factor of several hundred fold and dramatically increased cellular transport of molecules), and Baichwal teaches that addition of bioadhesive enhances the controlled release and adhesion of the bioactive molecules to the mucosa. There is a reasonable expectation of success, since Ryser teaches the enhancing the cellular uptake of protein hormones or polypeptide hormones, such as insulin, and Baichwal teach the controlled release and mucosa adhesion of wide variety of different types of drugs, including analgesics, anti-inflammatory agents, anti-tussive agents, hormone, antibiotics, antacids, anti-viral agents, etc (see claim 3).

27. Furthermore, in regards to the ranges, the MPEP states the following: Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. *"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."* *In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)* (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("*The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.*"); *In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969)* (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). Therefore, there is a motivation to optimize since the normal desire of scientist is to improve upon what is

already known through routine optimization, with the reasonable expectation that optimization of the known ranges would at least lead to a optimal compound that would lead to optimal treatment conditions.

Obviousness Double Patenting

28. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
29. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.
30. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

31. Claims 1-10 and 15-34 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-13, 18-26, 29-33 and 36-38 of copending Application No. 11/034,706 (US 2005/0215475).

Although the conflicting claims are not identical, they are not patentably distinct from

each other because if one of ordinary skill in the art practiced the claims of co-pending application, one would necessarily arrive at the instant invention and vice versa.

32. Claims 1, 4-13, 18-26, 29-33 and 36-38 of copending application is drawn to a pharmaceutical composition for transmucosal administration of a bioactive peptide or protein comprising the bioactive peptide or protein, a cationic polyamino acid, and a compatible buffer, at a pH between 3.0 and 8.0, further comprising tonicifying agent, viscosity-increasing agent, bioadhesive agent, and a preservative.

33. The instant claims are drawn to a pharmaceutical composition for transmucosal administration of a bioactive peptide or protein comprising the bioactive peptide or protein, a cationic polyamino acid, and a compatible buffer, at a pH between 4.0 and 6.0, and further comprising a tonicifying agent, a viscosity-increasing agent, a bioadhesive agent, and a preservative.

34. Therefore, if one of ordinary skill in the art practiced the claimed invention of the co-pending application, one would necessarily arrive at the claimed invention of instant application, and vice versa.

35. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

36. Claims 1-10 and 15-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-12, 17-25, 28-32, 34-37 and 39-41 of copending Application No. 11/628,123. Although the conflicting claims are not identical, they are not patentably distinct from each other

because if one of ordinary skill in the art practiced the claims of co-pending application, one would necessarily arrive at the instant invention and vice versa.

37. Claims 1, 3-12, 17-25, 28-32, 34-37 and 39-41 of copending application is drawn to a pharmaceutical composition for transmucosal administration of a bioactive peptide or protein comprising the bioactive peptide or protein, a cationic polyamino acid, and a compatible buffer, at a pH between 3.0 and 8.0, further comprising tonicifying agent, viscosity-increasing agent, bioadhesive agent, and a preservative.

38. The instant claims are drawn to a pharmaceutical composition for transmucosal administration of a bioactive peptide or protein comprising the bioactive peptide or protein, a cationic polyamino acid, and a compatible buffer, at a pH between 4.0 and 6.0, and further comprising a tonicifying agent, a viscosity-increasing agent, a bioadhesive agent, and a preservative.

39. Therefore, if one of ordinary skill in the art practiced the claimed invention of the co-pending application, one would necessarily arrive at the claimed invention of instant application, and vice versa.

40. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

41. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. H./
Examiner, Art Unit 1654

/Anish Gupta/

Primary Examiner, Art Unit 1654